

ISO 9001:2000—What's this radical revision all about?

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Here are answers to key questions about the latest changes to this series of international standards.

Since its launch in 1987, some 250,000 organizations around the world have registered to ISO 9000. Because of the tremendous response to this series of international standards that establish Quality Management System (QMS) requirements, many believe it to be the most influential initiative to grow out of the quality movement of the early '90s. One of the many reasons behind its success is the fact that the process of qualifying for the ISO 9000 standard can help an enterprise optimize its business and industrial processes.

In 1994, ISO 9000 was changed, but only marginally. Last year, it underwent a radical revision, and is currently referred to as ISO 9001:2000. These revisions require the quarter of a million organizations that had previously been certified to update their current quality

systems. In addition, it changes the ground rules for the hundreds of thousands of organizations that are either seeking registration or will seek registration in the future. National standards bodies, registrars, consultants, and the rest of the apparatus that has grown up around this standard must now contend with a whole new set of challenges and opportunities.

Like its predecessor, which is now officially known as ISO 9001:1994, ISO 9001:2000 is really a family of interrelated standards. In the new version there are three members of the family, each of which has a different function: ISO 9000 deals with fundamentals and vocabulary; ISO 9001, which is the heart of the new revision, states the requirements for the new system; and ISO 9004 provides guidance for implementation and fleshes out ISO 9001.

Given the impact of this revision and the costs it will entail, companies undoubtedly, and understandably, have many questions and concerns regarding ISO 9000:2000. For example: Do we have to register to the

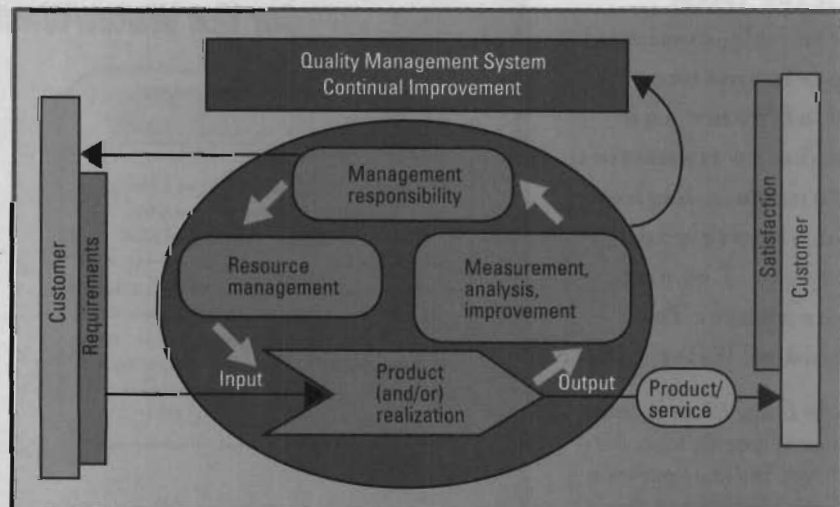


FIG 1: A Quality Management System stresses customer requirements on the "input" side and customer satisfaction on the "output" side.

new standard? How long is our current certification good for? Why the change? What's the difference between the old ISO and the new? How will it change the way we run our business? Who will benefit from the new standard? Who will be hurt? Will it be more difficult to implement the new ISO than the old? This article will address these and other questions.

How does ISO 9001:2000 compare with ISO 9001:1994?

The two standards offer a different model for quality. ISO 9001:1994 defines quality around 20 key elements a company uses to effectively and consistently produce the products and services it provides to customers. The standard was originally designed for application with manufacturing companies that produce widgets, although processing companies as well as service organizations have tailored the old ISO 9000 to apply to them. The primary purpose is to assure customers that the certified company produces products at a consistent level of quality. To register to ISO 9001:1994, as the cliché goes, "document what you do, do what you document, and be prepared to prove it."

The quality model in ISO 9001:2000 is quite different. Instead of 20 elements, it is based on a Process Model (Fig. 1). This model has no bias toward widget manufacturers. Instead of 20 elements, the Process Model, as laid out in the new ISO 9001, is composed of four sections: "Section 5: Management responsibility," "Section 6: Resource management," "Section 7: Product realization," and "Section 8: Measurement, analysis, improvement."

The other sections in ISO 9001 support the Model. Sections 0 through 3 provide background. "Section 4: Quality Management System" is a precursor to the Process Model itself, describing the obligations of the organization in establishing a documented quality system.

The four sections that lay out the process model in the standard also contain all the requirements for the new ISO stated in more generic and less prescriptive terms than in the previous 20-element model. This lack of specificity makes it easy for enterprises of all types to fit their operations to the new ISO.

On the other hand, although the new model may be simpler and less prescriptive than its predecessor, the requirements are a quantum leap forward, and in line with progressive think-

ing in the quality field. The model's four sections function similarly to the Plan-Do-Check-Act improvement process popularized by W. Edwards Deming (see Fig. 2). This is much more rigorous than the 1994 ISO's watchwords: "Do what you document, document what you do, and prove it."

The ISO 9001:2000 model—Is it a better fit for process & service companies?

Many of the twenty elements advanced in ISO 9001:1994 that relate to product control were developed with the discrete parts industries in mind, and most readily apply to widget makers: 4.8—Product Identification and Traceability; 4.—Process Control; 4.10—Inspection and Testing; 4.11—Control of Inspection, Measuring and Test Equipment; 4.12—Inspection and Test Status; 4.13—Control of Nonconforming Product.

In ISO 9001:2000, none of these specific elements exist. The closest equivalent in the new standard is "Section 7: Product Realization," which advances a far more open, generic architecture than its predecessor. Instead of figuring out how you need to twist what you do to match the standard, you determine what makes sense in your business and document it in a reasonable way.

The resulting quality system you document will be a comfortable fit for your organization. Moreover, you'll need less documentation for the new standard than for the old one. Much of the documentation specially created to meet the requirements of the old ISO 9000, especially first tier (policy-level) and second tier (systems-level) documentation, can be cut back or dispensed with altogether. ISO 9001:2000 requires a minimum of five system procedures in the four-section Process Model, compared with a minimum of 18 in the 20 elements of its predecessor. However, you may need more than five for ISO 9001:2000, since the standard requires that all processes be documented. There are no shortcuts, but there is flexibility.

In what ways does ISO 9001:2000 go beyond its predecessor?

In comparison with its predecessor, ISO 9001:2000 takes several quantum leaps forward. Here are the key ones:

- *Voice of the customer:* Even a cursory view of the graphic depiction of the Process Model in Figure 1 shows the power of the customer in the new standard. It's bookended by two dri-

The Improvement Cycle

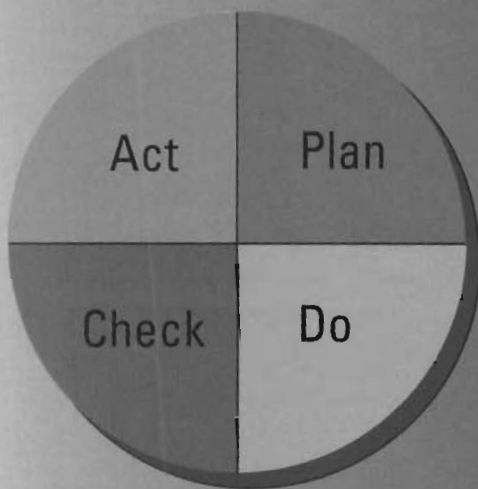


FIG. 2: The Plan-Do-Check-Act improvement process popularized by W. Edwards Deming.

vers: "Customer Requirements" drive the input and "Customer Satisfaction" drives the output. The organization will need methods in place to describe and monitor the needs and desires of each customer for each order, and will need processes and procedures in place to measure and analyze customer satisfaction.

Critics have long complained that a company could make concrete life preservers and still be reg-

istered to ISO 9000. ISO 9001:2000 helps put that criticism to rest.

- **Continual improvement:** Under ISO 9001:2000, it won't be enough for an organization simply to measure customer satisfaction; it will need to improve the level of satisfaction. It will also have to measure and improve internal processes. Continual (aka, continuous) improvement is a core theme in the new version of ISO 9000, and inherent in the model's Plan-Do-Check-Act structure.

Continual improvement is one of the essential goals of quality. Continually improving product/service uniformity, with consequent increased customer satisfaction, is a core value of Deming and TQM. Although many—including the authors of this article—believe that continual improvement was always implied in ISO 9000, continual improvement is now a clearly defined require-

ment throughout the 2000 revision.

- **Management responsibility:** Management had a role in the previous ISO 9000 in that it was required to establish quality policy, commit adequate resources, conduct a management review, and appoint a management representative to supervise the QMS. But, for the most part, under ISO 9001:1994, the quality management system was largely the responsibility of quality professionals.

Executive management plays a much more central role with the new standard. Management responsibility is expanded such that management presides over a multi-step version of the Plan-Do-Check-Act process. This includes the following requirements:

Step 1: Policy—Management is obligated to establish an appropriate quality policy that incorporates a commitment to continual improvement and meeting customer requirements.

Step 2: Objectives—This policy must establish a framework for reviewing quality objectives that are set "at relevant functions and levels within the organization."

Step 3: Planning—Objectives are set in conjunction with a plan that identifies the activities and resources necessary to achieve it. The planning "shall be consistent with other requirements of the quality system."

Step 4: Quality Management System—Management is responsible for ensuring that the organization establishes a QMS as a means of implementing the quality policy with its associated objectives and plans, as well as the requirements of the standard.

Step 5: Management review—Although ISO 9001:1994 required a management review, this element is much expanded in the new version. In this new model, management's check of the QMS specifically includes a review of policy and objectives to find opportunities for continual improvement. On the basis of this review, management is required to take actions, among other things, "relating to the improvement of the quality management system."

This process, which begins with setting policy and moves to management review with continual improvement as the output, is similar to the way the Plan-Do-Check-Act process is outlined in ISO 14001, the Environmental Management System Standard (see Figure 2). The compatibility between ISO 14001 and the new ISO 9000 should permit organizations

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to develop complementary systems for the two standards. [Appendix A of ISO 9001:2000 offers tables that show the correspondence between ISO 9001 and ISO 14001.]

• **Resource management:** The 1994 standard contains a paragraph (4.1.2.2) that requires management to provide necessary resources. It also contains requirements for training (4.18). These kernels are expanded in the 2000 revision to be one of the four clauses, "6.0 Resource Management," in the Process Model. The section spells out a wide range of specific resources, including human resources, that management leadership must provide or make available—that is, adequate numbers of competent people, the training necessary to assure competence, infrastructure, work environment (i.e., resources that affect safety, ergonomics, hygiene, etc.), suppliers and partners, and financial resources. These advances are embodied in the standard's eight Quality Management Principles shown in the sidebar, 3.0 Quality Management Principles. They emphasize the importance of customer focus, leadership, involvement of people at all levels, the process approach, systems and objectives, continual improvement, importance of accurate data and analysis, and the significance of supplier relationships—a mirror image of the focus on the customer.

If you've already registered to ISO 9000, do you have to start over?

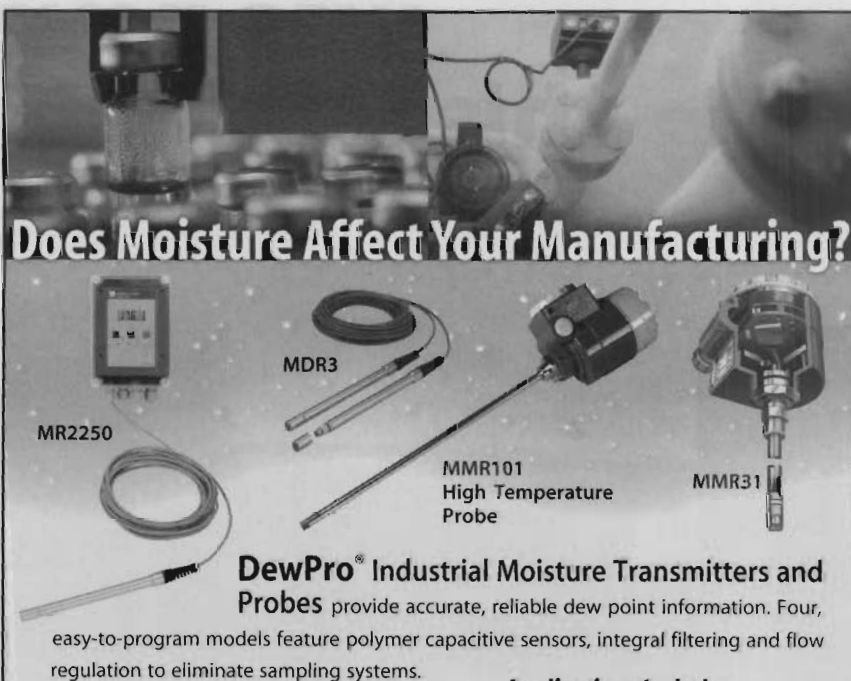
Every element of its predecessor can be mapped onto the new ISO 9000. For example, you can use ISO 9001:1994's Product Identification and Traceability, Process Control, Inspection and Testing, Control of Nonconforming Product, and Inspection and Test Status for ISO 9001:2000's "Section 7: Product Realization," if that's what you want. Moreover, because the new version requires written procedures, the familiar four-tier pyramid structure for documentation need not change, although it can be

simplified under the new standard, e.g., Policy Manual and Tier 1 procedures can be combined.

On the other hand, much of the existing documentation may need to be remapped and expanded to meet the requirements of ISO 9001:2000. In many

cases these revisions can be substantial. As an indication of the degree of change, 12 elements in ISO 9001:1994 have been reduced to sub-clauses in its successor.

Also, some new procedures will need to be produced to accommodate



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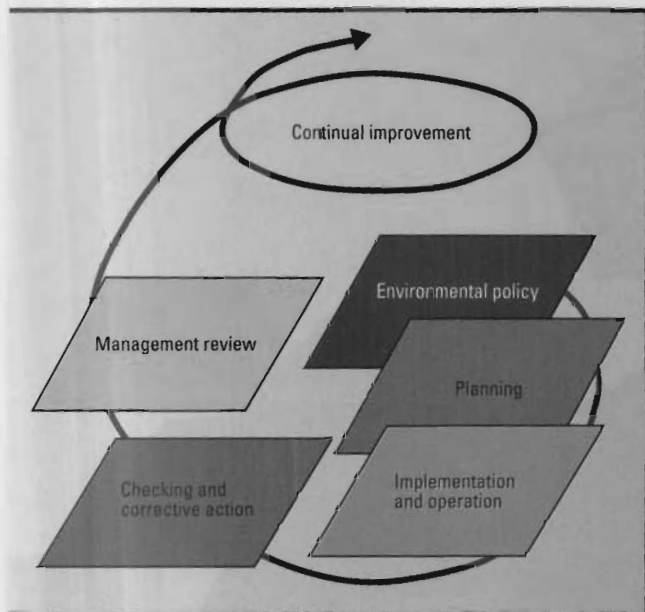


FIG. 3: Environmental management system for ISO 14001.

new requirements and subject matters. For example, there is nothing in ISO 9001:1994 that addresses elements in its successor such as 5.2 Customer Focus, 5.4 Planning, 5.5.4, Internal Communication, 6.2 Human Resources, 7.2.1 Identification of customer requirements, 7.2.3 Customer Communication, 8.2.1 Customer Satisfaction, 8.5 Improvement, and so on.

However, this needn't be as overwhelming as it seems. Much of what's new in ISO 9001:2000 will not be all that new to many well-run companies. Virtually every business

enterprise, organization or entrepreneur understands that to be successful an organization must:

- Have an effective strategic business planning process in place,
- Carefully monitor the needs and requirements of its customers,
- Satisfy its customers,
- Have a sufficient array of metrics to measure the performance of its internal processes and its success at satisfying its customers,
- Continually seek to improve its operations, its products and its services in order to succeed, grow, and to prosper.

Most well-run organizations will already have business processes in place to reach at least some of these objectives, which correspond to the requirements of ISO 9001:2000. Under the new standard, once formalized and disciplined, these business processes will become procedures folded into the business or quality management system required by ISO 9001:2000. Many companies may be far closer

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How does the transition work for companies already registered to ISO 9001, ISO 9002, or ISO 9003?

The transition to the new standard is essentially the same whether a company was registered ISO 9001, 9002 or 9003. ISO 9001:2000 contains a clause ("1.2 Permissible Exclusions") for excluding or modifying requirements so that companies registered under the old ISO 9002 and ISO 9003 can adapt their quality management systems to ISO 9001:2000. ISO 9002 and 9003 thus become obsolete.

The three ISO 9001:2000 documents—ISO 9000, ISO 9001, and ISO 9004—have been circulating in various draft forms since December 1998. ISO 9001:2000 is scheduled to be published as an International Standard (IS) in the fourth quarter of 2000.

Upon publication, an organization will have a maximum of three-years to adopt the new standard. In those three years, quality management systems conforming to either the 1994 or 2000 standard will be acceptable. To meet the deadline, it is expected and encouraged that organizations will start adopting the new requirements during their surveillance audits. Thus, if all goes according to plan, the conversion process should be complete by the beginning of 2004.

The Draft International Standard (DIS),

which was published at the end of 1999, is expected to be the same as the final draft, except for cosmetic changes. As a result, companies as well as registrars and consultants have begun taking steps to anticipate the transition. The first registrations were scheduled for December 2000, and companies are beginning to announce that they have been certified to the new standard.

As a rule of thumb, organizations that are already in the process of registering to the old ISO 9000 standard may want to continue on that track. However, most companies would be advised to adjust their target and seek registration to the new standard. Those that are committed to implementing the old version of ISO 9000, should begin modeling their system around ISO 9001:2000 in anticipation of the conversion that must follow.

How do we implement the new standard?

In general, the implementation process shouldn't be significantly different for the 2000 revision than it was for the previous version—with one important exception: under ISO 9001:1994 an organization could choose to exclude activities they performed such as design control (4.4) from the scope of their registration and seek certification to ISO 9002; under

3.0 Quality Management Principles

Principle 1—Customer-focused organization: Organizations depend on their customers and, therefore, should understand current and future customer needs, meet customer requirements and strive to exceed customer expectations.

Principle 2—Leadership: Leaders establish unity of purpose and direction of the organization. They should create and maintain the internal environment in which people can become fully involved in achieving the organization's objectives.

Principle 3—Involvement of people: People at all levels are the essence of an organization and their full involvement enables their abilities to be used for the organization's benefit.

Principle 4—Process approach: A desired result is achieved more efficiently when related resources and activities are managed as a process.

Principle 5—System approach to management: Identifying, understanding and managing a system of interrelated processes for a given objective improves the organization's effectiveness and efficiency.

Principle 6—Continual improvement: Continual improvement should be a permanent objective of the organization.

Principle 7—Factual approach to decision making: Effective decisions are based on the analysis of data and information.

Principle 8—Mutually beneficial supplier relationships: An organization and its suppliers are interdependent, and a mutually beneficial relationship enhances the ability of both to create value.

to satisfying the requirements of ISO 9001:2000 than a comparison with their current ISO 9000 based quality management system suggests.

ISO 9001:2000—Who does it help and who does it hurt?

The new ISO 9001 will benefit everyone the old ISO 9001 did, except much more so. By incorporating such advances as continual improvement and customer satisfaction, the new standard yields a more effective platform. It will help companies improve their operations and increase their competitiveness. With these improvements, customers will also benefit. As a result, ISO 9001:2000 will have far more weight with customers than did its predecessor.

Many companies have a separate QMS and business management system. ISO 9001:2000 encourages enterprises to combine the two. Such a combination should result in a streamlined organization devoted to a single model in which quality and business objectives are managed together. This is far more efficient and effective, and closer to the Business Excellence model contemplated in the Baldrige Awards.

While ISO 9000 was originally designed for manufacturing organizations, over the years it has also been adapted to process and service organizations. However, in many cases the fit was problematic and results seemed jury-built. So in many areas, ISO 9000 hasn't really caught on. Most certifications have been to manufacturing organizations, particularly those that produce discrete parts/products.

By contrast, because the new version is purposely more generic, it can be as readily applied to a chemical distributor, medical facility, or school as to a factory. This should increase the appeal of the standard to new classes of enterprise. With this broader appeal, the number of certifications under the 2000 revision should continue to grow.

The downside of the new standard is that it will, over time, require currently certified organizations to invest time and resources in meeting or adapting to its requirements. Some organizations will find this to be less of a challenge than others. For example, well-run companies with strategic/business planning processes and procedures in place to measure customer satisfaction will have a head start. Companies that have achieved ISO 9000 as a means of improving their business processes will also have an edge, since ISO 9001:2000 will move them further down the path they were already on.

Companies that have made only a minimal commitment to ISO 9000, who embraced it as a necessary evil—only to gain a marketing advantage or meet the demands of customers—may feel that the new ISO 9000 hurts them. Though these companies will, in fact, have to make the investment in time and effort that certification requires, which can be painful, the fact remains that ISO 9001:2000 offers considerable advantages to them and their customers.

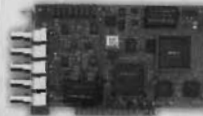
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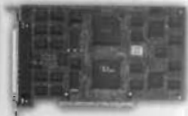
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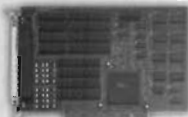
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ISO 9001:2000, businesses will no longer have the option of excluding activities they perform. In other words, under the new standard, if you do it, you must include it as part of your ISO 9001 system.

In a typical conversion, you will be asked to perform the following steps:

1. Get copies of the standard and review them. Although ISO 9001 is the key document, since it contains the requirements, ISO 9004 is also central. ISO 9004 provides guidance and fleshes out ISO 9001, which is generic and sparsely written.

2. Set up a core implementation or conversion team. If possible, reconstitute the team that you used in your original registration effort. This team will bear the primary responsibility for managing the initiative.

3. Contact your registrar to discuss options and obtain input. If you decide you don't have the expertise internally to carry out the transition, consider hiring an outside consulting and training organization.

4. Conduct a gap analysis to determine the gaps between your current systems and the requirements of the new ISO 9000. It's useful to start with Annex B of ISO 9001, which provides tables that show the correspondences between the 1994 and 2000 versions.

However, the gap analysis should not be confined to your quality management system. You should also consider the elements of your business management system and other business processes that may be candidates for incorporation into ISO 9001:2000. For example, if you survey your customers to get feedback on your organization's products and performance, you at least have the initial groundwork for the customer satisfaction process required in the new version.

5. Determine how you should structure your documentation. The simplest way to organize the conversion of your current documentation is to remap it to the new system without changing the existing numbering or organization. You could then use an index or matrix that shows how the two systems relate. This may be simpler in the short term, but could create

complexities down the road.

The alternative is to renumber and restructure your current documentation into the new system. This will take more work up front, but will create a more streamlined system in the long run.

6. Determine whether you have new training needs. You may wish, for example, to seek out instruction in setting up a business operating system based on the Plan-Do-Check-Act process, in establishing a continuous improvement system or in designing customer satisfaction processes.

Conclusion

By incorporating such factors as customer satisfaction and continual improvement, ISO 9001:2000 moves closer to the principles of TQM than its predecessor. At the same time, it retains the discipline of third-party assessment, registration, and surveillance that has made ISO 9000 so successful. It's an inevitable evolution that offers substantial benefits to organizations, their customers, and their suppliers.

About the authors

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The authors, Clyde Pearch and Jill Kitka, will be available to answer any questions you may have about this article. He can be reached at 800-508-9044 during normal business hours.

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